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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER LAM, ANN Y	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/839,778

Applicant(s)

HERRON ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,8-11 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,8-11 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, 5,747,272, and further in view of Sawai et al., 4,224,304.

Jackowski discloses the invention substantially as claimed. More specifically, Jackowski discloses a method comprising applying a sample (col. 11, lines 1-12, and col. 22, lines 14) to an assay device (col. 8, lines 59-65) with multiple probes (antibodies, col. 19, lines 26-28) to simultaneously detect multiple analyte markers (col. 22, lines 12-19, and col. 29, lines 33-39) having known parameters indicative of an acute metabolic or disease state, (cardiac disorder, col. 9, lines 36-45; and column 19, lines 8-14); substantially determining concentrations of each of the analytes (col. 29, lines 38-39); concurrently evaluating the presence of a plurality of analytes (see col. 29, line 35-38, disclosing detecting presence and amount of markers, and simultaneous detection and measurement); continuing the determination until the combination of the amount of analytes has been reliably determined to be present in an amount indicative of the metabolic or disease state, (see column 29, lines 51-63); and reporting said determination in an amount indicative of the metabolic or disease state, (see column 29,

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lines 51-63; and col. 9, line 64 – col. 10, line 4, disclosing obtaining results to make a diagnosis).

Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches various means of detection techniques, including measuring light signals (col. 28, lines 1-11). Jackowski teaches that various different detection and measurement technologies for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-39.) Jackowski teaches that various devices that may be used include those that include solid supports in the form of plates, tubes or beads (col. 23, lines 5-7.) Moreover Jackowski teaches that in addition to the devices disclosed, other techniques and corresponding sensor device may be used, including continuous/random access assay apparatuses (col. 26, lines 22-29.)

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (as recited by claim 1.)

Sawai et al. however disclose a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44.) Thus, Sawai et al. teach a method of measuring light signal generated from the reaction of an analyte with a reactive element, correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, wherein the light signal is indicative of a rate of reaction between the analyte and the reactive element as claimed by Applicants. Sawai et al. teach that the disclosed

invention provides an extremely high precision by short-time measurements (col. 11, lines 45-48.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method taught by Sawai et al. to determine the amount of analyte binding generally taught by Jackowski because Jackowski suggest that other known methods and devices may be used to determine the amount of analyte binding and also because Sawai et al. teach that the disclosed invention provides the advantage of providing an extremely high precision by short-time measurements. Moreover, the skilled artisan would have reasonable expectation of success in utilizing the Sawai et al. technique for determining concentration in the Jackowski method because Jackowski teach that various means of detection techniques, including measuring light signals, may be used (col. 28, lines 1-11) and that the devices that may be used include those that include solid supports in the form of plates, tubes or beads (col. 23, lines 5-7, and col. 29, lines 31-39), and both Jackowski and Sawai et al. teach utilizing antibodies.

As to claim 2, Applicants recite that concurrently determining continues after reporting results and the method further comprises reporting further results of concurrent determination. Jackowski teaches determining an amount of each marker simultaneously to yield meaningful data (col. 22, lines 15-19), and Sawai et al. teach determining the rate of increase in absorbance per unit time for comparison with a calibration curve (col. 11, lines 22-44). The reporting is indicated by the plotted curve, and a subsequent determination of rate of increase during this time period is deemed to

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be the step of continuing the determination after reporting. That is, each measurement is one determination, and each plot in the curve (or recorded data resulting in the plot) indicates a reporting step. As to the limitation regarding concurrently determining, this limitation is taught by Jackowski as explained earlier.

As to claim 3, Applicants recite that the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points. Jackowski teaches determining the level of each marker (column 22, lines 6-12), and Sawai et al. teach determining the rate of increase in absorbance per unit time for comparison with a calibration curve (col. 11, lines 22-44). Each evaluation of absorbance is deemed to be a step of evaluating.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction (see Jackowski, col. 1, lines 63-67.)

As to claim 14, the marker comprises myoglobin (see Jackowski, e.g., col. 37, lines 66-67.)

As to claim 15, the analyte is a cardiac specific marker (see Jackowski, col. 1, lines 63-67, and col. 7, lines 34-37.)

As to claims 16-19, the analyte comprises troponin as claimed (see Jackowski, col. 7, lines 34-37.)

As to claim 20, the analyte comprises creatine kinase (see Jackowski, col. 5, lines 29-31.)

As to claim 21, the creatine kinase comprises CK-MB (see Jackowski, col. 5, lines 29-31.)

2. Claims 1-3, 6, 8-11 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, 5,747,274, in view of Carter et al., 4,608,344.

Jackowski teaches the invention substantially as claimed. More specifically, as to claim 1, Jackowski discloses a method comprising applying a sample (col. 11, lines 1-12, and col. 22, lines 14) to an assay device (col. 8, lines 59-65) with multiple probes (antibodies, col. 19, lines 26-28) to simultaneously detect multiple analyte markers (col. 22, lines 12-19, and col. 29, lines 33-39) having known parameters indicative of an acute metabolic or disease state, (cardiac disorder, col. 9, lines 36-45; and column 19, lines 8-14); substantially determining concentrations of each of the analytes (col. 29, lines 38-39); concurrently evaluating the presence of a plurality of analytes (see col. 29, line 35-38, disclosing detecting presence and amount of markers, and simultaneous detection and measurement); continuing the determination until the combination of the amount of analytes has been reliably determined to be present in an amount indicative of the metabolic or disease state, (see column 29, lines 51-63); and reporting said determination in an amount indicative of the metabolic or disease state, (see column 29, lines 51-63; and col. 9, line 64 – col. 10, line 4, disclosing obtaining results to make a diagnosis).

Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches various means of detection techniques, including measuring

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light signals (col. 28, lines 1-11). Jackowski teaches that various different detection and measurement technologies for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-39), including fiber optic waveguide techniques (col. 27, lines 48-49.) Moreover Jackowski teaches that in addition to the devices disclosed, other techniques and corresponding sensor device may be used, including continuous/random access assay apparatuses (col. 26, lines 22-29.)

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (as recited by claim 1.)

Carter et al. however teach determination of the concentration of a species (analyte) in solution by measuring the rate, which is concentration dependent, for its combination with a specific reactant, in which a layer of analyte-reactant product is formed at the surface of a waveguide into which a light signal is injected and in which the layer changes the optical properties thereof and such modification being measured and used for the determination (col. 1, lines 7-20). Carter et al. teach that a variety of bioactive molecules in low concentration can be determined, including detection of antigens in an immunoassay type reaction (col. 1, lines 20- 26.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method taught by Carter et al. to determine the amount of analyte binding generally taught in the Jackowski method because Jackowski suggest that other known methods and devices may be used to determine the amount

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of analyte binding and also because Carter et al. teach that the disclosed invention provides the advantage of detecting even low concentrations. Moreover, the skilled artisan would have reasonable expectation of success in utilizing the Carter et al. technique for determining concentration in the Jackowski method because Jackowski teaches that various means of detection techniques, including measuring light signals, may be used (col. 28, lines 1-11) and that the devices that may be used include fiber optic waveguide techniques (col. 27, lines 40-57), and both Jackowski and Carter et al. teach utilizing antibodies for performing immunoassays.

As to claim 2, Applicants recite that concurrently determining continues after reporting results and the method further comprises reporting further results of concurrent determination. Jackowski teaches determining an amount of each marker simultaneously to yield meaningful data (col. 22, lines 15-19), and Carter et al. teach recording the reaction rate over a period of time (col. 13, lines 26-44.) Each recording is a reporting of a determination. As to the limitation regarding concurrently determining, this limitation is taught by Jackowski as explained earlier.

As to claim 3, Applicants recite that the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points. Jackowski teaches determining the level of each marker (column 22, lines 6-12), and Carter et al. teach recording the reaction rate over a period of time (col. 13, lines 26-44.) Each recording is a reporting of a determination, and each determination is part of an evaluation.

As to claim 6, each reactive element is immobilized on a waveguide surface (see Carter et al., col. 22, lines 49-50.)

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface (see Carter et al., col. 18, lines 60-63.) (It is noted that Applicants do not specify what kind of pattern.)

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the reactive element has coupled with the analyte (see Carter et al., col. 21, lines 23-27.)

As to claims 10 and 11, the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element (col. 1, lines 7-10.) As to the simultaneous determination, this is taught by Jackowski as explained above.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction (see Jackowski, col. 1, lines 63-67.)

As to claim 14, the marker comprises myoglobin (see Jackowski, e.g., col. 37, lines 66-67.)

As to claim 15, the analyte is a cardiac specific marker (see Jackowski, col. 1, lines 63-67, and col. 7, lines 34-37.)

As to claims 16-19, the analyte comprises troponin as claimed (see Jackowski, col. 7, lines 34-37.)

As to claim 20, the analyte comprises creatine kinase (see Jackowski, col. 5, lines 29-31.)

As to claim 21, the creatine kinase comprises CK-MB (see Jackowski, col. 5, lines 29-31.)

Response to Arguments

Applicants' arguments filed March 5, 2007 have been considered but are not persuasive.

Applicants argue on page 5 that contrary to the Office's assertion at page 4 of the Office action of November 28, 2006, amended independent claim 1 does not require that acts of "applying" and "determining" be effected separately from one another. Examiner does not find any use of the word "applying" on page 4 or any part of the Office action of November 28, 2006. It is believed that Applicants are referring to Examiner's statement on page 4 that "the use of capillary action for flow of serum or plasma as disclosed by Jackowski (col. 30, line 65) does not prevent the three different [markers] from being detected concurrently. That is, the flow of a sample and the detection step are two distinct steps". This statement however does not relate to *Applicants' claim 1* as currently or previously amended but rather refers to the *Jackowski* invention. It is meant to emphasize that the Jackowski example utilizing capillary action to move a sample (the example of which had been referred to by Applicants during prosecution) is *not* evidence that the Jackowski immunoassays are not or cannot be performed simultaneously (i.e., concurrently) because the step of moving the sample, e.g., via capillary action, is a different step from the step of

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analyzing the different immunoassays, which is disclosed by Jackowski as being simultaneous.

Applicants also assert on page 6 of the response that the Board of Patent Appeals and Interferences read Jackowski as disclosing a method that includes the “substantially simultaneous” evaluation of a plurality of analytes, pointing to the Board’s decision on pages 6-7. Applicants also state that the Board also noted that “concurrent” evaluation is different from “substantially simultaneous” evaluation, pointing to page 6 of the Board’s decision on page 6.

Applicants argue that the teachings of Jackowski relate to end-point assays, and thus Jackowski does not expressly or inherently describe a method that includes concurrently determining rates of reaction as required by amended claim 1. Applicants further submit that Jackowski does not expressly or inherently describe a method in which a sample is applied to an assay device that carries a plurality of reactive elements, and that a presence of a plurality of analytes in the sample may be concurrently evaluated.

Applicants’ arguments however are not persuasive. Page 6 of the Board’s decision (first full paragraph) only states that Applicant’s term “substantially simultaneously” reads on Jackowski’s definition of simultaneous, i.e., a shortened period of time. It does not appear that the Board interpreted Jackowski to be a method of “substantially simultaneous” to the exclusion of simultaneous/concurrent, as asserted by Applicants, but rather that Jackowski *encompasses* substantially simultaneously,

such that Applicant's use of the term "substantially simultaneously" reads on Jackowski's definition of simultaneous.

Moreover, page 6, third full paragraph to page 7, first line, of the Board's decision states:

'The examiner finds, however, that "the term 'simultaneous' as used by Jackowski encompasses a concurrent evaluation of the sample, because Jackowski indicates that the **term 'simultaneous' includes an evaluation within a given period of time (col. 22, lines 8-9), and a concurrent evaluation is within a given period of time" and does not exclude concurrent analysis. Answer, page 7. In agreement with the Examiner, we note that the claims before us do not require concurrent evaluation, they require "substantially simultaneous" evaluation' (emphasis added.)**

Thus, the Board had agreed with Examiner on the point that the term 'simultaneous' as used by **Jackowski encompasses a concurrent** evaluation of a sample because Jackowski indicates that the term 'simultaneous' includes an evaluation within a given period of time, and a concurrent evaluation is within a given period of time and simultaneous does not exclude concurrent analysis. Stated another way, the Board upheld Examiner's interpretation that Jackowski's use of the term

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“simultaneous” does *not* mean within a given period of time but excluding at the same time. Moreover, it is noted that the Board reviewed claim 7 which included the limitation “rate of reaction”.

With respect to Applicants’ statement that the Board also noted that “concurrent” evaluation is different from “substantially simultaneous” evaluation, pointing to page 6 of the Board’s decision on page 6, Examiner notes that the Board is pointing out that *Applicants’* claims (as presented to the Board) did not require concurrent evaluation (because they recited “substantially simultaneously”, rather than simultaneously, or concurrently). It does not appear however that the Board was interpreting the term “substantially simultaneous” used by Jackowski to be within a period of time but excluding the same time (simultaneous or concurrent). See the Board’s decision on page 6, last two lines to page 7, first line, stating “In agreement with the Examiner, we note that the claims before us do not require concurrent evaluation, they require “substantially simultaneous” evaluation. In other words, the Board is not stating that Jackowski does not teach concurrent, but rather the Board was distinguishing between the term concurrent and Applicants’ claims reciting “substantially simultaneously”.

Applicants submit on page 6 of the response that Jackowski does not expressly or inherently describe a method in which a sample is applied to an assay device that carries a plurality of reactive elements, and that a presence of a plurality of analytes in the sample may be concurrently evaluated. Applicants assert that Jackowski instead describes that multiple assays for different analytes may be conducted on a single sample that is obtained at a single point in time and thus the amounts of markers that

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are simultaneously present in the sample may be accurately determined. Applicants state that different assays may be performed within a given time frame after the sample is obtained. Applicants further assert that as an example, Jackowski describes a device in which a sample moves by capillary action substantially linearly through three detection zones of a membrane at successive points in time, and that according to Jackowski, such assays are considered to be effected "simultaneously" even though they are not effected at the same point in time, or concurrently. Applicants state that the configuration and intended function (i.e., application of a sample to a sample well, wicking of the sample through the length of the membrane, and sequential passage of the sample through different detection zones at different points in time) prevent multiple analytes potentially within a sample from being concurrently assayed. As stated earlier, Examiner emphasizes that the use of capillary action for flow of the sample in the example disclosed by Jackowski does not prevent the three different markers from being detected concurrently because the step of moving the sample, e.g., via capillary action, is a different step from the step of analyzing the different immunoassays, which is disclosed by Jackowski as being simultaneous. Therefore the Jackowski example utilizing capillary action to move a sample is *not* evidence that the Jackowski immunoassays are not or cannot be performed simultaneously (i.e., concurrently).

Applicants further argue that claim 8 is also allowable because Jackowski does not describe the capture molecules to be in a pattern on the surface of a waveguide. Given the amendment to claim 1 from which claim 8 depends (to include the limitation

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regarding rate of reaction), the grounds for rejection of claim 8 is now rejected under Jackowski, 5,747,274, in view of Carter et al., 4,608,344.

Moreover Applicants argue on page 7 that the teachings of Jackowski are limited to conducting multiple end-point assays on the same sample, while the teachings of Sawai et al. are limited to evaluating rates of reaction of a single analyte and its corresponding capture molecule to provide an accurate indication of the amount of that analyte in a sample. Applicants further argue that neither Jackowski nor Sawai et al. provides any teaching or suggestion that would have motivated one of ordinary skill in the art to consider multiple rates of reaction between a plurality of analytes and corresponding reactive elements to diagnose an acute metabolic or disease state.

Examiner has emphasized that Jackowski teaches that in addition to the devices disclosed, other techniques and corresponding sensor device may be used, including continuous/random access assay apparatuses (col. 26, lines 22-29.) Jackowski teaches various means of detection techniques, including measuring light signals (col. 28, lines 1-11) and that various different detection and measurement technologies for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-39.) Jackowski teach that various devices that may be used including those that include solid supports in the form of plates, tubes or beads (col. 23, lines 5-7), as is relevant to the Sawai et al. method, and fiber optic waveguide techniques (col. 27, lines 48-49), as is relevant to the Carter et al. method. Thus, Jackowski suggests that other detection techniques and devices may be used to perform the disclosed method. Moreover, both Sawai et al. and Carter et al. teach

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advantages to their disclosed invention, which also provides a motivation to the skilled artisan to utilize their detection techniques. Examiner emphasizes again that the Board reviewed claim 7 which included the limitation "rate of reaction" and upheld the grounds for rejection. For the reasons set forth above, Applicants arguments are not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ANN YEN LAM
PATENT EXAMINER